

### **REMARKS**

By the present communication, claims 1 and 18 are amended and claims 29-35 are canceled without prejudice. Claims 16 and 39-42 are withdrawn from consideration although the remarks in the Office Action indicate that Claim 16 will be joined with Species A. Support for the amended claims can be found throughout the application as filed, including, but not limited to paragraph [0086] (legend to Table 1 on p. 44). Upon entry of the amendment, claims 1-28 and 36-44 will be pending.

The amendment is respectfully requested to be entered under 37 CFR 1.116(b)(1) because the amendment adopts the claim amendments suggested by the Examiner and requires no further search. Claim 1 was also amended to more clearly identify that the data matrices are generated for each of the first sample and the second sample. In view of the foregoing amendments and the following remarks, Applicant respectfully requests reconsideration of this application.

#### **I. Information Disclosure Statement**

The Office Action dated February 27, 2007, states that all of the references cited in the Information Disclosure Statement (IDS), filed on 1/5/04 and 9/13/04 have been entered and considered. However, Applicant notes that U.S. Patent No. 6,636,646 on page 1 of the 9/13/04 IDS was not initialed by the Examiner. Accordingly, Applicant respectfully requests that the Examiner consider this reference and initial form PTO-1449 and return a copy to the Applicant.

#### **II. Restriction Requirement and Rejoinder**

The Office Action states that “Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse.” However, Applicants respectfully point out that in the Restriction Requirement was traversed in part because the “magnitude, quantity, or quality of the data value” for nucleic acid expression, protein expression, and chromatographic profiles is meant to reflect the chemical or biological properties of the sample, *e.g.*, a chemical reaction or a binding interaction or other similar interactions known to those of skill in the art (see Specification,

paragraph [0022]) (See Response to Restriction Requirement, dated December 17, 2007). Consequently, Applicants identified the errors in the Restriction Requirement and request the Examiner to reconsider this requirement (see MPEP 821.01).

In the event that the Restriction Requirement is made final, Applicants respectfully request rejoinder of the unelected species upon allowance of the generic base claim. It is submitted that withdrawn claims 16 and 39-42 depend from claim 1, which is now allowable. Therefore, rejoinder is proper (MPEP 821.04).

### **III. Claim Rejections – 35 U.S.C. § 101**

Claims 1-28, 36-38, and 43-44 stand rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The Office Action states:

In the instant case, at least one embodiment of the claimed invention merely manipulates data sequences and performs a series of calculations without transforming an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Since the process merely manipulates data sequences and performs a series of calculations, and the process can be performed entirely in a computer or machine or human mind without using or making available for use the results of the manipulation to enable the functionality or usefulness to be realized.

(Office Action, p. 4).

In accordance with the Examiner's suggestion, Applicants have added a step to independent claims 1 and 18, which recites the outputting of the corresponding pairs of data points not eliminated by earlier steps in the method. Thus, the claimed methods produce a data set for the user in which the unreliable data has been removed. Support for this amendment can be found throughout the application as filed, including, but not limited to, the legend to Table 1, which applies the claimed method to an exemplary embodiment (microarray data), and states,

“The algorithm outputs the log2 of the mean of the 4 replicate normalized values.”  
(Specification, p. 44, emphasis added).

Compliance with § 101 may be established where the claimed invention produces a useful, concrete, and tangible result. The Federal Circuit has recognized that the transformation of data can produce a useful, concrete, and tangible result. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998). (“the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces ‘a useful, concrete and tangible result’ - a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.”). The process claimed in the pending claims produces a useful, concrete, and tangible result.

MPEP § 2106 states that for an invention to be “useful” it must satisfy the utility requirement of section 101. Claims 1-28 are directed to a practical application which produces a real-world result. MPEP § 2107.01(I). Claim 1 recites method for eliminating indistinguishable differentials from a direct comparison of a pair of samples. The specification states that indistinguishable differentials come from at least two sources:

The first source of unreliable data stems from data points that are indistinguishable from random background noise level of the experimental system. The second source of unreliable data comes from data points that lie above the background noise level, but that are substantially indistinguishable from their corresponding data points in a symmetrical matrix.  
(Specification, paragraph [0017], emphasis added).

Thus, removing the indistinguishable differentials produces a data set that is more reliable and less likely to be misleading or cause serious errors. The result is a more accurate comparison of the measured properties of two samples. Accordingly, the method of claim 1 and claims 2-28,

which depend therefrom, produce a practical, “real-world” result, and therefore satisfy the utility requirement.

MPEP § 2106 states that the “tangible requirement does require that the claim must recite more than a 35 U.S.C. 101 judicial exception, in that the process claim must set forth a practical application of that judicial exception to produce a real-world result.” MPEP § 2106 further states that “[i]t is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted ....” Such practical method and means of producing a beneficial result is reflected in independent claims 1 and 18. Specifically, the claimed methods output a data set to the user in which the unreliable data has been removed (*See* Specification, paragraph [0012]). The beneficial, real-world result is the elimination of indistinguishable differentials from data generated from the comparison of the two samples which results in the removal of unreliable data, providing a more robust comparison. The present methods may be used by, for example, persons performing gene expression analysis, protein expression profiling, nucleic acid sequence profiling, or analyzing oligochip data, seismic data, chromatographic data, thermal gravimetric data, and economic data. (See generally paragraphs [0018] and [0025]-[0028]). Consequently, claims 1-28 recite tangible subject matter.

With reference to the concrete requirement, MPEP § 2106 states that “[u]sually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again.” MPEP § 2106 goes on to state that the “opposite of “concrete” is unrepeatable or unpredictable.” Here, claim 1 recites a method comprising that results in “eliminating indistinguishable differentials from a direct comparison of the pair of samples.” It is beyond reasonable dispute that “eliminating indistinguishable differentials” is a result which can be assured. Further, the ranking and curve-fitting steps used to eliminate the indistinguishable differentials are based on the intensity values which once received, do not change. Therefore, the elimination of indistinguishable differentials is both repeatable and predictable for a given data

set. For at least these reasons, Applicants respectfully submit that independent claims 1-28 and 36-44 recite concrete subject matter.

Accordingly, Applicants respectfully submit that claims 1-28 and 36-44 as amended, satisfy the requirements of 35 U.S.C. § 101, and request that the Examiner withdraw this rejection.

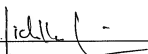
#### **IV. Conclusion**

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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